

WHAT IS CLAIMED IS:

1. An adjuvant, comprising:
 - a) a block copolymer of the general formula:
$$\text{HO}(\text{C}_2\text{H}_4\text{O})_a(\text{C}_3\text{H}_6\text{O})_b(\text{C}_2\text{H}_4\text{O})_a\text{H};$$
wherein (b) represents a number such that the molecular weight of the hydrophobic POP portion ($\text{C}_3\text{H}_6\text{O}$) is up to approximately 20,000 daltons and wherein (a) represents a number such that the percentage of hydrophilic POE portion ($\text{C}_2\text{H}_4\text{O}$) is between approximately 1% and 40% by weight; and,
 - b) a cationic surfactant.
2. The adjuvant of claim 1 wherein subscript (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 9000 Daltons and 15,000 Daltons and subscript (a) of the general formula represents a number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is between approximately 3% and 35%, preferably at or below 10%.
3. The adjuvant of claim 1 wherein subscript (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 9000 Daltons and subscript (a) of the general formula represents a number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is between approximately 3% and 5%.
4. The adjuvant of claim 1 wherein subscript (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 12000 Daltons and subscript (a) of the general formula represents a number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is approximately 5%.
5. The adjuvant of claim 1 wherein the block copolymer is CRL-1005.

6. The adjuvant of claims 1, 2, 3, 4 or 5 wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride, benzethonium chloride, cetramide, cetylpyridinium chloride and cetyl trimethylammonium chloride.

- 5 7. A polynucleotide vaccine formulation, comprising:
a) a population of polynucleotide molecules; and,
b) an adjuvant, the adjuvant consisting of a block copolymer of the general formula:



10 wherein (b) represents a number such that the molecular weight of the hydrophobic POP portion ($\text{C}_3\text{H}_6\text{O}$) is up to approximately 20,000 daltons and wherein (a) represents a number such that the percentage of hydrophilic POE portion ($\text{C}_2\text{H}_4\text{O}$) is between approximately 1% and 40% by weight; and,
c) a cationic surfactant,
15 wherein a portion of the polynucleotide vaccine molecule population are associated with the adjuvant and the remaining portion of the polynucleotide vaccine molecule population are free within a pharmaceutically acceptable buffer.

8. The polynucleotide vaccine formulation of claim 7 wherein subscript
20 (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 9000 Daltons and 15,000 Daltons and subscript (a) of the general formula of the block copolymer represents a number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is between approximately 3% and 35%, preferably at or below 10%.

25 9. The polynucleotide vaccine formulation of claim 7 wherein
subscript (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 9000 Daltons and subscript (a) of the general formula of the block copolymer represents a
30 number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is between approximately 3% and 5%.

10. The polynucleotide vaccine formulation of claim 7 wherein
subscript (b) of the general formula of the block copolymer represents a number such

that the molecular weight of the hydrophobe (C_3H_6O) is between approximately 12000 Daltons and subscript (a) of the general formula of the block copolymer represents a number such that the percentage of hydrophile (C_2H_4O) is approximately 5%.

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11. The polynucleotide vaccine formulation of claim 7 wherein the block copolymer is CRL-1005.

12. The polynucleotide vaccine formulations of claims 7, 8, 9, 10 or 11
10 wherein the cationic surfactant is selected from the group consisting of benzalkonium chloride, benzethonium chloride, cetramide, cetylpyridinium chloride and cetyl trimethylammonium chloride.

13. The polynucleotide vaccine formulation of claim 11 which is selected
15 from the group consisting of D118, D118a, and D121.

14. A method of inducing an immune response in an mammalian host
which comprises introducing the polynucleotide vaccine formulation of claim 7 into
said mammalian host.

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15. A method of inducing an immune response in an mammalian host
which comprises introducing the polynucleotide vaccine formulation of claim 8 into
said mammalian host.

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16. A method of inducing an immune response in an mammalian host
which comprises introducing the polynucleotide vaccine formulation of claim 9 into
said mammalian host.

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17. A method of inducing an immune response in an mammalian host
which comprises introducing the polynucleotide vaccine formulation of claim 10 into
said mammalian host.

18. A method of inducing an immune response in an mammalian host which comprises introducing the polynucleotide vaccine formulation of claim 11 into said mammalian host.

5 19. A method of inducing an immune response in an mammalian host which comprises introducing the polynucleotide vaccine formulation of claim 12 into said mammalian host.

10 20. A method of inducing an immune response in an mammalian host which comprises introducing the polynucleotide vaccine formulation of claim 13 into said mammalian host.

15 21. A polynucleotide vaccine formulation, comprising:
a) a population of polynucleotide molecules; and,
b) an adjuvant, the adjuvant consisting of a block copolymer of the general formula:



20 wherein (b) represents a number such that the molecular weight of the hydrophobic POP portion ($\text{C}_3\text{H}_6\text{O}$) is up to approximately 20,000 daltons and wherein (a) represents a number such that the percentage of hydrophilic POE portion ($\text{C}_2\text{H}_4\text{O}$) is between approximately 1% and 40% by weight;

- c) a cationic surfactant; and,
d) a non-ionic surfactant

25 wherein a portion of the polynucleotide vaccine molecule population are associated with the adjuvant and the remaining portion of the polynucleotide vaccine molecule population are free within a pharmaceutically acceptable buffer.

30 22. The polynucleotide vaccine formulation of claim 21 wherein subscript (b) of the general formula of the block copolymer represents a number such that the molecular weight of the hydrophobe ($\text{C}_3\text{H}_6\text{O}$) is between approximately 9000 Daltons and 15,000 Daltons and subscript (a) of the general formula of the block copolymer represents a number such that the percentage of hydrophile ($\text{C}_2\text{H}_4\text{O}$) is between approximately 3% and 35%, preferably at or below 10%.

23. The polynucleotide vaccine formulation of claim 21 wherein
subscript (b) of the general formula of the block copolymer represents a number such
that the molecular weight of the hydrophobe (C_3H_6O) is between approximately 9000
Daltons and subscript (a) of the general formula of the block copolymer represents a
5 number such that the percentage of hydrophile (C_2H_4O) is between approximately 3%
and 5%.

24. The polynucleotide vaccine formulation of claim 21 wherein
subscript (b) of the general formula of the block copolymer represents a number such
10 that the molecular weight of the hydrophobe (C_3H_6O) is between approximately
12000 Daltons and subscript (a) of the general formula of the block copolymer
represents a number such that the percentage of hydrophile (C_2H_4O) is
approximately 5%.

15 25. The polynucleotide vaccine formulation of claim 21 wherein the block
copolymer is CRL-1005.

26. The polynucleotide vaccine formulations of claims 21, 22, 23, 24 or 25
wherein the cationic surfactant is selected from the group consisting of benzalkonium
20 chloride, benzethonium chloride, cetramide, cetylpyridinium chloride and cetyl
trimethylammonium chloride.